

## REMARKS

Applicants have carefully reviewed the Final Office Action dated April 17, 2002. With this Amendment, Applicants have amended claims 1 and 3. Claims 1-9, 11-15 and 21 remain pending in this application.

The Examiner asserts that claims 1-9, 11-15 and 21 are rejected under 35 U.S.C. §102(e) as being anticipated by Heck in U.S. Patent No. 6,083,207.

Claim 1 has been amended to positively recite the inclusion of a valve sleeve distinct from the valve body, sheath, and medical device. Heck fails to teach a means for restricting fluid flow during the insertion of a medical device through the valve including the use of a valve sleeve. During the insertion of a medical device through the valve body, the valve must be substantially opened to allow the medical device to pass through. During this procedure, the valve body lumen is unobstructed, thus allowing unwanted fluid leakage through the valve and around the medical device.

The claimed valve sleeve restricts fluid flow while in a compressed position, while allowing the insertion of a medical device into the portion of the valve sleeve proximal to the compressed region. The distal portion of a medical device inserted into the valve sleeve substantially occludes the valve sleeve lumen, thus significantly restricting fluid loss when the valve is opened, allowing the medical device to pass through the valve sleeve lumen contained within the valve body. Applicants respectfully submit that these remarks and the amended claim language overcome the rejection under 35 U.S.C. §102(e) and that claim 1 is allowable.

Claim 2 depends from claim 1 and, therefore, is believed allowable for the same reasons as claim 1, and further because other limitations are recited.

Claim 3 has been amended to recite that the valve sleeve is used to restrict fluid flow during the insertion of a medical device through the valve. As stated above, Applicants respectfully submit that Heck fails to provide a means of restricting fluid flow during medical device insertion.

Claims 4-9 and 11 depend from claim 3 and, therefore, are believed allowable based on the above amendments and remarks, and further because of other limitations recited.

Claim 12 recites the inclusion of a distinct "tubular, flexible, proximal valve sleeve" in the introducer sheath assembly. Similar to claims 1 and 3, claim 12 is believed allowable based on the use of a valve sleeve not disclosed in Heck.

Claims 13 and 14 depend from claim 12 and, therefore, are believed allowable based on the above remarks, and further because of other limitations recited.

Claim 15 recites the use of a valve sleeve to restrict fluid flow through the valve body. Similarly, claim 15 is believed allowable based on the remarks regarding the above independent claims.

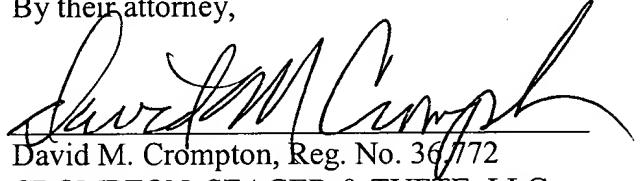
Claim 21 depends from claim 15 and, therefore, is believed allowable based on the above remarks, and further because of other limitations recited.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims, namely claims 1-9, 11-15 and 21, are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

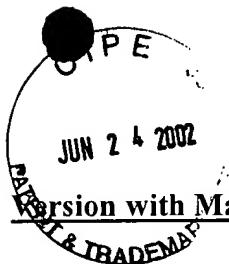
Michael S.H. Chu et al.

By their attorney,



David M. Crompton, Reg. No. 36772  
CROMPTON, SEAGER & TUFTE, LLC  
331 Second Avenue South, Suite 895  
Minneapolis, Minnesota 55401-2246  
Telephone: (612) 677-9050  
Facsimile: (612) 359-9349

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Version with Markings to Show Changes Made

In the Claims:

Claims 1 and 3 have been amended as follows:

1. (Once Amended) A valve for a tubular peel-away sheath having a lumen therethrough comprising:

a valve body having a lumen therethrough;

means for preferentially breaking said valve body along a predetermined location in response to applied force, such that said valve body lumen splits open upon breaking;

means for coupling said valve body to said peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen;

means for receiving a compressible valve sleeve [having a lumen therethrough for coupling said valve sleeve lumen to said valve body lumen; and] including a cavity defined therein;

a compressible valve sleeve having a lumen therethrough disposed at least in part within said cavity; and

means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through valve and valve sleeve lumen.

3. (Twice Amended) A breakaway valve for a tubular peel-away sheath, said sheath having an external surface, a lumen, and a proximal end comprising:

means for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end, wherein said means for reversibly restricting fluid flow include a valve sleeve having a lumen therethrough and means for compressing said valve sleeve;

means for breaking apart said fluid flow restricting means responsive to applied force; and

means for admitting a catheter distal end into said valve and selectively through said lumen of said valve sleeve.